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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,677	04/08/2004	Lisa Lynn Shafer	P-10966.00 US	8518
27581	7590	01/24/2008		
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MINNEAPOLIS, MN 55432-9924			EXAMINER GEDEON, BRIAN T	
			ART UNIT 3766	PAPER NUMBER
			MAIL DATE 01/24/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/820,677

Applicant(s)

SHAHER, LISA LYNN

Examiner

Brian T. Gedeon

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8-10, 15, 18-42, 54-67 and 130-199 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8-10, 15, 18-42, 54-67 and 130-199 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. This action is in response to the amendment filed 13 November 2007.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The 35 U.S.C. 102(b) rejections against claims 1-4, 8-10, 15, 54-65, and 139-199 under Rezai (US Publication no. 2002/0116030) made in the prior Office action is maintained.

3. Claims 18-20, 38-42, and 130-138 are rejected under 35 U.S.C. 102(b) and being anticipated under (US Publication no. 2002/0116030).

In regard to claims 18-20 and 38-42, Rezai teaches that it is known in the art to have a means for sensing electrical and chemical activity in the area of interest for regulation of treatment, para [0077]-[0078].

In regard to claims 130-138, figure 1 of Rezai shows the different locations for stimulating the sympathetic nerve chain, and includes the celiac ganglia as one of the regions.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The 35 U.S.C. 103(a) rejection against claims 63-67 under (US Publication no. 2002/0116030) made in the prior Office action is maintained.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-4, 8-10, 15, 17-42, 54-67, and 130-199 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 11/467,963. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim methods for attenuating an immune response and/or pro-inflammatory response by stimulation of a sympathetic neuron of the splenic nerve, splenic neurovascular bundle, periaxillary splenic nerve, etc.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. The provisional obviousness-type double patenting rejection made in the prior Office action against application 10/820,937 has been withdrawn in view that the copending application has been abandoned.

Allowable Subject Matter

Claims 21-37 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

8. Applicant's arguments filed 13 November 2007 with respect to claims 1-5, 8-10, 15, 54-65, and 130-199 as being anticipated by Rezai have been fully considered but they are not persuasive. Applicant argues that the Rezai reference teaches in contrast to the claimed subject matter in that Rezai does not teach or suggest treating a patient suffering from or at risk of a disorder mediated by the immune response or a pro-inflammatory mediator by stimulating a sympathetic neuron. The Examiner provides support for in paragraph [0060] where Rezai teaches that the sympathetic nerve ganglia can be stimulated to treat the gall bladder, liver and pancreas by providing rest to the organs in states of inflammation. The Examiner considers that the "providing rest" as

taught by Rezai alleviates the symptoms of the inflammation and must therefore attenuate or inhibit the immune or inflammatory response. Further, the sympathetic ganglia may include the celiac ganglion as a stimulation point (figure 1) as claimed.

9. With regard to Applicant's argument that it would not be obvious to stimulate an end organ based on the disclosure of Rezai, the Examiner respectfully disagrees. It is known in the art and in Rezai that stimulation of an efferent autonomic nerve has an ultimate result in a response the end organ that the nerve controls, paragraph [0027]. Similarly it is known that direct stimulation of the organ itself will create the same response. Therefore it would not have been beyond one of ordinary skill in the art at the time the invention was made to directly stimulate the end organ since it would involve substitution of a known technique for another known technique to yield predictable results, which would constitute a matter of choice in design.

10. Applicant's arguments see Remarks, filed 13 November 2007, with respect to claims 18-42 and 66-70 as being unpatentable under Rezai in view of Tracey (US Patent no. 6,610,713) have been fully considered and are persuasive. The rejection of above claims in the last Office action has been withdrawn.

11. Applicant's arguments see Remarks, filed 13 November 2007, with respect to claims 1-4, 8-10, 15, and 54-67 as being unpatentable under King (US Patent no. 6,058,331) have been fully considered and are persuasive. The rejection of above claims in the last Office action has been withdrawn.

12. Applicant's arguments see Remarks, filed 13 November 2007, with respect to claims 18-42 and 66-70 as being unpatentable under King in view of Tracey (US Patent

no. 6,610,713) have been fully considered and are persuasive. The rejection of above claims in the last Office action has been withdrawn.

13. Applicant's arguments see Remarks, filed 13 November 2007, with respect to claims 1-4, 18-42, 17, 54-62, 66-70, and 140-199 as being unpatentable under Tracey in view of Sherwood ("Human Physiology: From Cells to Systems") have been fully considered and are persuasive. The rejection of above claims in the last Office action has been withdrawn.

14. Applicant's arguments see Remarks, filed 13 November 2007, with respect to claims 18-42 and 66-70 as being unpatentable under Tracey in view of Sherwood further in view of Whitehurst (US Patent no. 6,735,475) have been fully considered and are persuasive. The rejection of above claims in the last Office action has been withdrawn.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tracey (US Patent nos. 6,838,471 and 6,610,713) both pertain to a method for attenuating an immune response and/or pro-inflammatory inhibitor based on stimulation of a parasympathetic neuron of the vagus nerve.

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272-3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:
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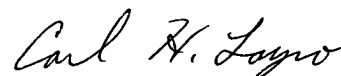
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Brian T. Gedeon
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CARL LAYNO
PRIMARY EXAMINER